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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,140	01/22/2004	Hing C. Wong	TNA-005.05	6085

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EXAMINER	
BORGEEST, CHRISTINA M	
ART UNIT	PAPER NUMBER
1649	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/764,140	Applicant(s) WONG ET AL.	
	Examiner Christina Borgeest	Art Unit 1649	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 12 July 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *12 July 2007*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *37,39-42 and 47-55*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☒ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). IDS filed 25 May 2007
13. ☐ Other: _____.

/Elizabeth C. Kemmerer/
Primary Examiner, Art Unit 1646

Continuation of 3. NOTE: Regarding claim 37, which was amended to recite "SEQ ID NO: 4 or fragment thereof." The amendment was not entered because further consideration would be required to determine if "fragments" of antibodies are enabled for treatment of sepsis (for generally in the protein art, "fragments" are not enabled). In addition, "fragments" is very broad.

Continuation of 11. does NOT place the application in condition for allowance because: Applicants argue:

"A skilled artisan at the time that the '806 application (aka '065 patent) was filed would have known that sepsis could be treated by addressing the resulting disseminated intravascular coagulation phenotype. For example, it was known from Levi et al. 1994 (document number EO from the IDS filed on January 19, 2006) that "endotoxin-induced activation of coagulation appears to be mediated by the tissue factor-dependent pathway." The '806 specification teaches that antibodies of the invention could be used to detect native human tissue factor in a biological sample, such as that from a patient suffering from septic shock (Column 12, lines 19-38), and that antibodies of the invention could then be administered to a primate, such as a human, to prevent or reduce thromboses (Column 9, lines 63-65) as are manifested during sepsis. Moreover, the '806 specification teaches therapeutic compositions (Column 9, line 66 to Column 10, line 22), methods of administration (Column 10, lines 32-39), and therapeutic dosages (Column 10, lines 39-62) relevant to the treatment of sepsis. Finally, the specification provides a literal basis for the term "septic shock syndrome" at page 6, first paragraph."

The arguments have been considered but are not found persuasive for the following reasons:
-Levi et al. is not incorporated by reference in the '065 patent, so their teachings are not part of the disclosure of the '065 patent.
-The citation from the '065 patent at column 12, lines 19-38 actually says the antibodies could be used to DETECT native human TF in a biological sample, and that the samples could be taken from mammals suffering a long list of other disorders, of which septic shock syndrome (which is a complication following sepsis) is one. The claims are drawn to treatment of sepsis, so detection of TF in biological samples from patients suffering from a long list of diseases is not sufficiently enabling for the currently recited claims.
-The citation of the '065 patent at column 9, lines 63-65 make no mention of sepsis, only says "to reduce thrombosis such as restenosis."
-The other citations of the '065 patent do not provide any support for treatment of sepsis.
-The instant specification at p. 6 1st paragraph does not define sepsis, however, a definition can be found on medline at nlm.nih.gov/medlineplus/ency/article/000666.htm. Since the instant claims are drawn to treatment of sepsis and not merely detection of TF, Applicants arguments that the '065 patent provides enablement and written description are not found persuasive.